

PATENT

Attorney Docket No. AME-06352

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In re Application of: William D Huse *et al.*

Serial No.: 09/434,870

Group No.: 1642

Filed: 11/04/99

Examiner: L. Helms

Entitled: **Methods of Optimizing Antibody Variable
Region Binding Affinity**

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**SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT**

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Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being hand delivered to Examiner L. Helms in Group 1642.

Dated:

5-1-02

By:

Albert N. Molinari

Sir or Madam:

ALBERT N. MOLINARI

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

Applicants have become aware of the following printed publications which may be material to the examination of this application:

- WO 99/42075; Applicants submit that this PCT application is not available as a prior art reference MPEP 716.10. The Examiner is requested to note that the present application has a priority date of 10/14/99 (the filing date of provisional application serial number 60/159,689). The 1999 PCT publication was published less than one year prior (e.g. August 1999). All of the inventors of the presently claimed invention appear on the PCT. These three inventors contributed to the method of humanization resulting in a humanized and higher affinity antibody. The inventors named on the PCT publication not appearing as inventors on the instant patent application did not make an inventive contribution to the method of humanization resulting in a humanized and higher affinity antibody.

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inventors on the instant patent application did not make an inventive contribution to the method of humanization resulting in a humanized and higher affinity antibody.

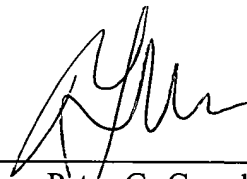
- U.S. Patent 6,312,693 to Aruffo *et al.*; Applicants submit that this CIP patent is not available as a prior art reference. The Examiner is requested to note that the present application has a priority date of 10/14/99 (the filing date of the provisional application serial number 60/159,689). U.S. Patent 6,312,693 was filed as a CIP of U.S. serial number 09/026,291 (filed February 19, 1998) on February 10, 1999, and thus the new matter in U.S. Patent 6,312,693 is only entitled to a priority date of February 10, 1999, which is less than one year before the priority date of the instant application. U.S. Patent 6,312,693 lists, as co-inventors, all of the inventors of the presently claimed invention. These three inventors contributed to the method of humanization resulting in a humanized and higher affinity antibody. The inventors named on U.S. Patent 6,312,693 not appearing as inventors on the instant patent application did not make an inventive contribution to the method of humanization resulting in a humanized and higher affinity antibody.

The following reference was cited by an Examiner in an independent application submitted by the Applicants.

- U.S. Patent No. 5,977,322 to Marks *et al.* is generally directed to isolation and optimization of scFvs which can bind human c-erbB-2. The sFvs are expressed from a phage vector in either soluble form or as gene III fusions, depending on the host strain of *E. coli*.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: April 30, 2002



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